UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

CAREFIRST OF MARYLAND, INC., GROUP HOSPITALIZATION AND MEDICAL SERVICES, INC., CAREFIRST BLUECHOICE, INC., and CFA, LLC d/b/a CAREFIRST ADMINISTRATORS, on behalf of itself and all others similarly situated,

Plaintiffs,

v.

JOHNSON & JOHNSON and JANSSEN BIOTECH, INC.

Defendants.

Civil Action No. 2:23-CV-00629

District Judge Jamar K. Walker

Magistrate Judge Lawrence R. Leonard

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

OPPOSITION TO DEFENDANTS JOHNSON & JOHNSON AND JANSSEN BIOTECH, INC.'S MOTION TO DISMISS PLAINTIFFS' AMENDED CLASS ACTION COMPLAINT

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INTRODUCTION

J&J's omissions explain why the Complaint should be sustained. *First*, J&J does not contest its monopoly power in the market for ustekinumab. This concession is crucial: "a [Sherman Act] § 2 violation will have occurred where, for example, the *dominant* competitor in a market acquires a patent covering a substantial share of the same market that he knows when added to his existing share will afford him monopoly power."[1] Here, J&J concedes that it was, at all relevant times, the dominant competitor. It also does not contest that it acquired biosimilar manufacturing patents—patents aimed at *enhancing* competition in the market for ustekinumab—that it had no use for other than to *exclude* competitors. Nor does it contest that it used these patents to prevent competitors from selling more affordable ustekinumab.

Second, J&J does not contest that its *own clinical trial protocol* rendered its '307 patent invalid. The plaintiffs—health benefit providers (the purchasers, for short)—allege that J&J affirmatively misrepresented the meaning of this clinical trial protocol *and* omitted key prior art in violation of its duty of candor and good faith to the U.S. Patent and Trademark Office (PTO). These alleged misrepresentations were material and violated *Walker Process*.[2]

J&J makes a pure legal argument in the face of the uncontested facts—that both the '307 and Momenta patents were valid and therefore are immune from antitrust liability. J&J selectively quotes *SCM Corp. v. Xerox Corp.*'s statement that "where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws."[3] But J&J omits *SCM*'s full holding: "Where, however, the *acquisition itself* is

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[1] *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1205 (2d Cir. 1981) (emphasis added). The Fourth Circuit credited *SCM*'s understanding of the balance between antitrust and patent law in *International Wood Processors v. Power Dry, Inc.*, 792 F.2d 416, 427 (4th Cir. 1986).

[2] *Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172 (1965).

[3] *SCM*, 645 F.2d at 1206; *see* Def. Br. 11 (quoting this language from *SCM*).

unlawful, the subsequent exercise of the ordinarily lawful exclusionary power inherent in the patent would be a continuing wrong, a *continuing unlawful exclusion of potential competitors*."[4] By *SCM*'s own terms, therefore, J&J's acquisitions were unlawful.

The health benefit providers seek damages and injunctive relief to ensure that J&J cannot continue to force the nation's buyers of prescription drugs to pay monopolist prices on ustekinumab—a crucial immunotherapy used to treat children and adults with a variety of serious auto-immune diseases. The Court should deny J&J's motion and allow the plaintiffs to proceed with this important antitrust litigation.

FACTS

The facts are quite simple. In 2001, J&J filed a patent application on its invention of ustekinumab. ECF No. 36 ¶ 98.[5] In the summer of 2005, the PTO granted this patent, and J&J's legitimate term of patent monopoly over the drug began. ¶ 99. In 2009, the FDA granted J&J approval to sell ustekinumab, under the brand name Stelara, to treat moderate to severe plaque psoriasis. ¶ 101. In 2013, the FDA approved the drug to treat psoriatic arthritis; in 2016, to treat Crohn's disease. ¶¶ 102-03. All these diseases are inflammatory autoimmune disorders that involve disfunction of the same protein pathway—Interleukin 12 (IL-12) and Interleukin 23 (IL-23). ¶¶ 92-97. Stelara targets that pathway, therein treating those diseases. *Id*. Crohn's is closely related to a fourth, similar autoimmune disease: ulcerative colitis (UC). Both are inflammatory bowel conditions impacting the digestive tract. *Id.*

Since the early 2000s, scientists have understood the role of IL-12 and IL-23 in the pathogenesis of inflammatory bowel disease, including both Crohn's and UC. ¶ 112. Doctors

[4] *SCM*, 645 F.2d at 1206 (emphasis added).

[5] All cites to ¶ numbers are to the Amended Complaint, ECF No. 36.

often use the same monoclonal antibodies to treat these disorders. ¶¶ 113-116. After a round of successful clinical trials and FDA approval for use of ustekinumab to treat Crohn's, J&J turned to obtaining FDA approval for treatment of UC. ¶¶ 117-120. When J&J launched its UC clinical trial, it knew ustekinumab would be an effective treatment for the disorder. ¶ 118. We know this because J&J said so right in its clinical trial protocol: "'considering the similarities in the genetics and biology of UC and Crohn's disease, it is reasonable to assume that ustekinumab will also be effective in UC.'" ¶ 122. Unsurprisingly, the trials were successful, and in October 2019, the FDA approved Stelara to treat UC. ¶ 139.

Ustekinumab's effectiveness in treating multiple autoimmune disorders has made it a blockbuster drug. J&J has grossed more than *$60 billion* in Stelara sales. ¶ 106. Today, Stelara remains J&J's best-selling drug both in the United States and worldwide, delivering nearly $7 billion in net U.S. sales and roughly $10.9 billion in worldwide sales in 2023. *Id.* Since 2009, when the FDA granted J&J approval to sell Stelara, "J&J has had, and continues to have, monopoly power in the market for ustekinumab in the United States." *Id.*

To protect and further this monopoly, J&J took two unlawful steps. *First*, on September 24, 2019, J&J applied for a patent on the use of ustekinumab to treat UC. ¶ 136. Not only did J&J's own clinical trial protocol anticipate this application, rendering it invalid, but numerous studies published before J&J applied for the patent made it obvious and, thus, unpatentable. ¶¶ 140-152. Nonetheless, by affirmatively misrepresenting its clinical trial protocol and omitting the published studies (in violation of PTO rules), J&J procured an invalid patent (the '307 patent) that it used to extend its monopoly over ustekinumab. The '307 patent expires in 2039. ¶ 151.

Second, in 2020, J&J acquired a *biosimilar* drug manufacturer—Momenta Pharmaceuticals—and its *biosimilar* manufacturing patents. Although these patents covered

inventions that were intended to *enhance* biosimilar competition, J&J used these patents to *block* competition and unlawfully extend its monopoly an additional fifteen months. ¶ 247. For a drug that rakes in $7 billion per year, a 15-month monopoly extension amounts to a King's Ransom, forced upon plaintiffs and the class.

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'"[6] "Factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true."[7]

ARGUMENT

The complaint alleges an anticompetitive scheme comprised of J&J's unlawful acquisition of the '307 and Momenta patents. The "goal, purpose, and effect" of this scheme was to "delay and/or block ustekinumab biosimilars from entering the market, maintain its monopoly in that market, and maintain its supra-competitive prices for Stelara." ¶¶ 282, 296, 310, 331. In *Continental Ore*, the Supreme Court instructs that "[t]he character and effect" of the anticompetitive conduct "are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole."[8] Courts must look beyond the individual acts, standing alone, and assess "the economic effects of the challenged conduct on consumers, competitors,

[6] *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

[7] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotation omitted).

[8] *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962); *see also SD3, LLC v. Black & Decker (U.S.) Inc.*, 801 F.3d 412, 425 (4th Cir. 2015) ("Actions that might seem otherwise neutral in isolation can take on a different shape when considered in conjunction with other surrounding circumstances."); *Robertson v. Sea Pines Real Estate Cos.*, 679 F.3d 278, 291 (4th Cir. 2012) (sustaining an antitrust claim based on alleged acts that "cumulatively enabled the defendants to exclude" competitors).

and the alleged violator itself."[9] Here, the scheme extended J&J's monopoly an additional fifteen months, forcing the class to overpay by more than $1 billion. ¶¶ 92, 199, 247. While J&J urges the Court to treat each "disparate" fact separately, Def. Br. 25, that approach invites error as it conflicts with *Continental Ore*. The purchasers plead plausible claims because, taken as a whole, they allege a scheme which violates antitrust and trade practices acts and unjustly enriches J&J.

Even viewed in isolation, both of J&J's acts—procuring the '307 patent by fraud on the PTO and acquiring Momenta's biosimilar patents to extend its monopoly over the ustekinumab market—were unlawful.

I. J&J's acquisition of the Momenta patents constitutes unlawful monopolization of the market for ustekinumab.

A. The antitrust laws forbid a monopolist in a market from acquiring patents covering that same market to maintain or further its monopoly power.

Section 2 of the Sherman Act states that "[e]very person who shall monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States . . . shall be deemed guilty of a felony . . . ."[10] State law similarly allows indirect purchasers, like the health benefit providers here, to sue antitrust violators for damages.[11] To plead monopolization

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[9] *Advanced Health-Care Servs. v. Radford Cmty. Hosp.*, 910 F.2d 139, 148 (4th Cir. 1990).

[10] 15 U.S.C. § 2. J&J neglects to separately counter the purchasers' attempted monopolization count, treating it as identical to the monopolization claim. Def. Br. 1-2. But the standards for attempted monopolization and monopolization differ. Attempted monopolization has three elements "(1) a specific intent to monopolize the relevant market; (2) predatory or anticompetitive acts in furtherance of the intent; and (3) a dangerous probability of success." *M & M Med. Supplies & Serv., Inc. v. Pleasant Valley Hosp., Inc.*, 981 F.2d 160, 166 (4th Cir. 1992). The purchasers meet this standard, and J&J waived any argument to the contrary.

[11] As J&J concedes, the state antitrust statutes under which the health benefit providers bring their claims follow and incorporate federal antitrust precedent. Def. Br. 26 & n.15 (collecting citations to statutes and cases on harmonization of federal and state antitrust law). Thus, to the extent the purchasers allege an antitrust violation under federal law, their state law claims survive. *See In re Zetia (Ezetimibe) Antitrust Litig.*, No. 2:18-md-2836, 2019 WL 1397228, at *22 (E.D. Va. Feb. 6, 2019) ("[T]he various complaints have alleged sufficient facts to state a

under § 2 of the Sherman Act and its state law analogues, a plaintiff must adequately allege the defendant "(1) possess[ed] monopoly power in the relevant market and (2) willful[ly] acqui[red] or maint[ained] that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[12]

Here, J&J *does not challenge* the health benefit provider's allegations as to the first prong: at all relevant times (including when J&J acquired the Momenta patents), J&J was (and is) a monopolist in the U.S. market for the sale of ustekinumab. This concession is pivotal to the motion as "[c]onduct that might otherwise be lawful may be impermissibly exclusionary under antitrust law when practiced by a monopolist."[13] As the Fourth Circuit has held, "'a monopolist is not free to take certain actions that a company in a competitive . . . market may take, because there is no market constraint on a monopolist's behavior.'"[14]

This principle has been applied to a monopolist's acquisition of patents. *SCM* is the seminal decision on this topic. There, the Second Circuit emphasized "[p]atent acquisitions are *not* immune from the antitrust laws."[15] Instead, a monopolization "violation will have occurred where . . . the *dominant* competitor in a market acquires a patent covering a substantial share of the same market that he knows when *added* to his existing share will afford him monopoly power."[16] *SCM* observed "[i]n scrutinizing acquisitions of patents under § 2 of the Sherman Act,

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claim under §§ 1 and 2 of the Sherman Act. The EPPs' derivative state claims rest on the same allegations and likewise should not be dismissed on this basis."), *report and recommendation adopted as modified*, 400 F. Supp. 3d 418, 433 (E.D. Va. 2019).

[12] *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966); *see Advanced Health-Care*, 910 F.2d at 147.

[13] *E.I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d 435, 441 (4th Cir. 2011).

[14] *Id.* (quoting *LePage's, Inc. v. 3M*, 324 F.3d 141, 151-52 (3d Cir. 2003)); *see Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601-04 (1985)).

[15] *SCM*, 645 F.2d at 1205 (emphasis added).

[16] *Id.* (emphasis added).

the focus should be upon the market power that will be conferred by the patent in relation to the *market position* then occupied by the *acquiring party*."[17] "That the asset acquired is a patent is irrelevant; in such a case the patented invention already has been commercialized successfully, and the magnitude of the transgression of the antitrust laws' proscription against willful aggregations of market power outweighs substantially the negative effect that the elimination of that class of purchasers for commercialized patents places upon the patent system."[18]

Two district courts have recently applied *SCM* to sustain facts parallel to those pled here. First, in *Bio-Rad Laboratories, Inc. v. 10X Genomics, Inc.*, a purchaser (10X) sued a patent holder (Bio-Rad) alleging that Bio-Rad's purchase of a competitor (RainDance) and its patent portfolio was unlawful because it enabled Bio-Rad to extend its monopoly power.[19] Relying on *SCM*, the *Bio-Rad* court confirmed, "[t]he acquisition of patents can constitute monopolization when 'the dominant competitor in a market acquires a patent covering a substantial share of the same market.'"[20] The court then held 10x's "allegation that Bio-Rad possesses a 90% market share at the time of the [RainDance] acquisition, and further increased its market share by acquiring RainDance, is sufficient to allege a Sherman Act violation because it indicates that a dominant competitor further entrenched its monopoly by consolidating its hold on the market."[21]

Likewise in *ABS Global, Inc. v. Inguran, LLC*, the Western District of Washington denied

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[17] *Id.* at 1208 (emphasis added).

[18] *Id.* In *SCM*, the patent holder was not a monopolist *at the time it acquired* the relevant patents (instead, the patent acquisitions enabled it to build monopoly power). *Id.* at 1209.

[19] *Bio-Rad Laboratories, Inc. v. 10X Genomics, Inc.*, 483 F. Supp. 3d 38, 48 (D. Mass. 2020). In the relevant market, 10X was a *purchaser* of Bio-Rad's products, not a competitor producer, just like the health benefit providers here. *Id.* at 62.

[20] *Id.* at 63 (quoting *SCM*, 645 F.2d at 1205, 1210).

[21] *Id.* at 67. 10X alleged that Bio-Rad violated the Sherman Act with respect to three product markets. The court found that Bio-Rad only possessed monopoly power in one market at the time of acquisition and held that 10X adequately pled a § 2 violation as to that market only.

a defendant patent holder summary judgment on the plaintiff's claim that its acquisition of patents violated § 2.[22] The plaintiff alleged that Inurgan monopolized the sexed bovine semen processing market because it either acquired or held the exclusive licenses to dozens of patents related to this market.[23] Although "acquiring and asserting valid patents is absolutely protected by the patent laws 'in the absence of monopoly,'" "because of their tendency to foreclose competitors from access to markets or customers or some other inherently anticompetitive tendency, they are unlawful under § 2 if done by a *monopolist*."[24] The court concluded that "a reasonable jury could find that [the defendant's] accumulation of patents . . . was part of an unlawful effort to maintain its monopoly in violation of § 2 of the Sherman Act."[25] *ABS Global* clarified an additional point relevant here: patent acquisition need not increase market power to be unlawful.[26] "The case law instructs that the relevant question here is *not* whether the patent acquisitions actually enhanced [the acquirer's] market power, but rather whether they reflect [the acquirer's] intent to *maintain* monopoly power through anticompetitive means."[27]

The Fourth Circuit adopted the Second Circuit's (*SCM*'s) approach to balancing antitrust and patent law in *International Wood Processors v. Power Dry, Inc.*[28] There, the Court rejected the very same "patent immunity" argument J&J offers in this motion. Def. Br. 10-11. The Fourth

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[22] *ABS Global, Inc. v. Inguran, LLC*, No. 14-cv-503-WMC, 2016 WL 3963246, at *12 (W.D. Wis. July 21, 2016).

[23] *Id.* at *2-3, 12. Of note, the defendant acquired one company and its patents. *Id.* at *3.

[24] *Id.* at *18 (emphasis added) (quoting *City of Mishawaka, Ind. v. American Elec. Power Co., Inc.*, 616 F.2d 976, 986 (7th Cir. 1980)).

[25] *Id.* at *20.

[26] *Id.* at *19 (citing *Ford Motor Co. v. United States*, 405 U.S. 562, 576 n.11 (1972) ("Even constitutionally protected property rights such as patents may not be used as levers for obtaining objectives proscribed by the antitrust laws.")).

[27] *Id.*

[28] *International Wood Processors*, 792 F.2d 416 (4th Cir. 1986).

Circuit held that a conspiracy between a patentee and licensee to terminate the license of a third party "constitutes an anticompetitive extension of the patent monopoly" despite the patentee's protestations that it was merely exercising its valid patent rights.[29]

These decisions—and others like them—have led the country's foremost antitrust and patent law scholars to agree that "patent acquisitions by *dominant* firms that threaten to increase or perpetuate the acquirer's dominance have been treated as exclusionary practices under § 2 of the Sherman Act."[30] In short, a monopolist's acquisition of patents covering the market it monopolizes to further maintain that monopoly power—especially where the firm does not use the patents, but rather acquires them to exclude competitors—violates § 2.

B. The complaint adequately alleges J&J unlawfully acquired the Momenta patents to further its monopoly power.

The complaint alleges that J&J, while a monopolist in the U.S. market for ustekinumab, acquired the Momenta biosimilar patents to maintain, extend, and further entrench that monopoly power. First, J&J does not contest the purchasers' allegation that J&J possessed monopoly power in the market for ustekinumab when it acquired the Momenta patents. ¶¶ 163, 312. Second, J&J does not contest that it acquired the Momenta patents. The Momenta patents cover methods of manufacturing *biosimilar* (read: competitor) versions of biologic drugs like ustekinumab. ¶¶ 157-161. J&J did not need the patents to manufacture Stelara; it had done so for years without the

[29] *Id.* at 425, 429.

[30] Herbert Hovenkamp, et al., IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law, § 14.03 Intellectual Property Acquisitions By Dominant Firms (2023), *available at* 2015 WL 9447772; Holmes, Acquiring separate intellectual property assets, Intellectual Property and Antitrust Law § 12:3 ("[W]here a firm with a clearly dominant market position aggressively appropriates key intellectual property assets from outsiders on an exclusive basis for the purpose of thereby suppressing competition . . . [t]he possible repercussions of such behavior under the Sherman, Clayton and FTC Acts are apparent."); *see also United States v. Singer Mfg. Co.*, 374 U.S. 174, 189 (1963) (settlement of patent-related disputes and acquisition of exclusive licenses for exclusionary purposes is unlawful).

patents. ¶ 165. Thus, J&J's only use for the Momenta patents was to do that which the inventions were designed to prevent: impair biosimilar competition for medicines like ustekinumab. ¶ 166.

J&J's patent acquisition enabled it to "improperly maintain[] its monopoly power and substantially reduce[] and harm[] competition." ¶ 313. Because J&J was "the *dominant*"—indeed, the *only* "competitor"—in the U.S. market for ustekinumab and "acquire[d] patent[s] . . . that [it] kn[ew] when added to [its] existing share will afford [it] monopoly power,"[31] J&J's acquisition of the Momenta patents was unlawful under § 2. Where "the acquisition itself is unlawful, the subsequent exercise of the ordinarily lawful exclusionary power inherent in the patent [is] a continuing wrong, a continuing unlawful exclusion of potential competitors."[32]

C. The FTC's and DOJ's failure to sue J&J over its Momenta acquisition does not immunize J&J from private antitrust claims.

Citing *zero* authority, J&J claims the FTC's and the DOJ's pre-merger review of J&J's Momenta purchase sanctioned its acquisition of the Momenta patents, and therefore dismissal is required. Def. Br. 4, 12. But there is no basis to infer the FTC affirmatively reviewed the patents for competitive concerns, and federal agency inaction does not require dismissal. To the contrary, the FTC's and DOJ's failure to act within 30 days in response to a pre-merger notification under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR) has zero bearing on a post-merger, private antitrust damages case based on acquisitional conduct. The antitrust laws rely heavily on complimentary private enforcement to provide additional checks on anticompetitive behavior. The House Report accompanying the addition of pre-merger review to HSR emphasized this very point.[33] Or, as the Supreme Court put it, "antitrust laws are best served by

[31] *SCM*, 645 F.2d at 1205.

[32] *Id.* at 1206.

[33] *Nader v. Air Transp. Ass'n of Am.*, 426 F. Supp. 1035, 1040 (D.D.C. 1977) (quoting the

insuring that the private action will be an ever-present threat to deter anyone contemplating business behavior in violation of the antitrust laws."[34]

Next, J&J notes that Clayton Act § 7 outlaws an acquisition of assets as anticompetitive, and the health benefit providers "make no effort to challenge J&J's acquisition of Momenta under Section 7." Def. Br. 12. J&J then implies—without citing *any* authority—that the purchasers' decision not to bring a § 7 claim for monopolization allows for dismissal. Not so. As previously explained, courts routinely sustain § 2 style monopolization claims where the defendant "willful[ly] acqui[red] or maint[ained market power]" by acquiring patents.[35]

D. J&J proximately caused the purchasers' antitrust injury.

J&J next lobs a series of causation arguments. None hit. *First*, J&J argues that its unlawful patent acquisitions (both the Momenta and '307 patents) did not "cause" delayed competition because the biosimilar manufacturers could have launched at risk rather than settling, risking costly liability for patent infringement.[36] According to J&J, because the Biologics Price Competition and Innovation Act (BPCIA) does not trigger an automatic stay of FDA approval, J&J's actions did not *cause* the biosimilars' delayed entry.[37] J&J's argument

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House Report's statement that the "antitrust laws clearly reflect the national policy of encouraging private parties (including consumers) to help enforce the antitrust laws in order to protect competition through compensation of antitrust victims, through punishment of antitrust violators, and through deterrence of antitrust violations.").

[34] *Perma Life Mufflers, Inc. v. Int'l Parts Corp.*, 392 U.S. 134, 139 (1968).

[35] *Grinnell*, 384 U.S. at 570-71; *see* Section I.A. (detailing numerous sustained Sherman Act § 2 claims based on unlawful patent acquisitions).

[36] The purchasers do not allege the Momenta patents were invalid; J&J maintains their validity.

[37] J&J cites *Mayor & City Council of Balt. v. AbbVie Inc.*, 42 F.4th 709, 712 (7th Cir. 2022) for its uncontroversial explanation of the BPCIA ("[T]he competitor is free to sell at risk of an adverse outcome in the patent litigation."). Def. Br. 7. Nowhere does *AbbVie* support J&J's argument that plaintiffs may not bring antitrust actions against biologic makers who have kept competitors off the market because the BPCIA permits at-risk launch.

amounts to a claim that all biosimilar manufacturers (regulated by the BPCIA) must infringe valid patents before bringing an antitrust action.

The law has no such mandate. An antitrust violation is the proximate cause of an injury even if there are additional independent causes.[38] "Even if an antitrust violation is not the material cause of an injury and the only material cause is some intervening conduct, courts have consistently found the causation requirement satisfied and the chain of causation intact where that intervening conduct was the foreseeable consequence of the original antitrust violation."[39]

This Court rejected a nearly identical defense argument in another generic suppression case. In *Ryan-House v. GlaxoSmithKline*, a pharmaceutical manufacturer argued that buyers of its drug Augmentin failed to allege the defendant "enforce[d]" its patent through successful, affirmative litigation, therein causing the plaintiffs' antitrust injury.[40] Augmentin was an antibiotic, also not subject to the Hatch-Waxman Act's automatic 30-month stay.[41] The defendant similarly argued the plaintiffs could not show causation because it did not foreclose generic entry through successful, affirmative patent litigation. This Court disagreed and sustained the antitrust claims.[42] Just so here: by either suing or threatening to sue every competitor that attempted to

[38] *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 114 n. 9 (1969) ("It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury . . . ."); *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 628 (E.D. Pa. 2011) ("[E]ven if intervening conduct contributed to a plaintiff's injury, defendant's conduct still might be a proximate cause of the injury.").

[39] *Flonase*, 798 F. Supp. 2d at 628 (collecting cases). Irrespective, determinations of proximate cause and intervening cause belong to the jury; *Middle East Broadcasting Networks, Inc. v. MBI Global, LLC*, 689 F. App'x 155, 164 (4th Cir. 2017).

[40] *Ryan-House v. GlaxoSmithKline*, Civ. A. No. 2:02-cv-442, at 8 (E.D. Va. March 12, 2004) (attached as Ex. C).

[41] *See Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344 (Fed. Cir. 2004).

[42] *Ryan-House*, Ex. C at 8.

sell biosimilar ustekinumab, J&J "did all that [it] could . . . to enforce [its] patent[s]," completely foreclosing the market.[43] *See* ¶ 231 (listing J&J's settlements).

Second, J&J contends that the biosimilar manufacturers' lack of FDA approval for their ustekinumab products causes the purchasers' injury—not their settlements with J&J. First, J&J concedes that Amgen *has* FDA approval to sell biosimilar ustekinumab. Def. Br. 22-23. Thus J&J's argument regarding FDA approval does not provide grounds to dismiss the complaint; the undisputed facts demonstrate at least one biosimilar could have come to market absent J&J's patent acquisitions. And the complaint alleges that competition from Amgen alone would have saved payers substantial sums. ¶ 199. Second, as for the yet-to-be approved biosimilars, J&J's argument ignores the multitude of decisions holding that a lack of FDA approval does not break the chain of causality. For example, in *In re Restasis*, a pharmaceutical manufacturer made the exact same argument, and the court rejected it: "It is [] reasonable to infer, as plaintiffs ask me to do, that the [delay] resulting from the patent infringement litigation led the FDA to divert its resources away from the [generic applications] at issue."[44]

The purchasers ask this Court to draw the same inference.[45] But for the J&J settlements, the biosimilars would have obtained the approval necessary to compete with Stelara. ¶ 294. All

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[43] *Id.*

[44] *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 159 (E.D.N.Y. 2018) ("The FDA may have prioritized reviewing applications for other generic drugs, because, even if tentative approval were granted to the [applications], a drug subject to a stay would not be able to enter the market for some time . . . ."); *In re EpiPen (Epinephrine Injection USP) Mktg., Sales Pracs. & Antitrust Litig.*, 336 F. Supp. 3d 1256, 1293-94 (D. Kan. 2018) (holding that the plaintiffs adequately alleged that "defendants' alleged unlawful . . . settlements caused both the potential competitors' delay in entering the [product] market and their delay in securing FDA approval"); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 336 (D.R.I. 2017) (same); *Flonase*, 798 F. Supp. 2d at 630 (same, but the conduct was sham citizen petitions).

[45] *See Short v. Hartman*, 87 F.4th 593, 614 (4th Cir. 2023) (in a motion to dismiss, a court "draw[s] all reasonable inferences in favor of the plaintiff").

seven of the biosimilar manufacturers who reached settlements with J&J have advanced development of ustekinumab biosimilar products and have applied for FDA approval.[46] What incentive does the FDA have to rush approval of these applications when their settlements with J&J preclude them from selling until 2025?

Third, J&J argues that even if the purchasers adequately plead *Walker Process* fraud, this fraud does not cause their injuries, because plaintiffs have not shown that the '307 patent—by itself—could have kept competitors off the market. Def. Br. 20. First, the '307 patent was one of a suite of unlawfully acquired patents that J&J used to successfully exclude its competitors. ¶¶ 183, 191, 195, 201-07, 210-18, 220-22, 226-29, 231. That J&J did not move for a preliminary injunction against Amgen based on this patent is irrelevant: J&J does not contest that it used this patent to reach settlement agreements with biosimilars, delaying competition. Nor does J&J contest that, had it chosen to do so, it could have used the '307 patent to enjoin competitors from selling ustekinumab for all its indications, not just the UC indication which it held patents.[47]

Fourth, J&J claims that the Momenta patents were "narrow" and therefore could not be used "to stop the launch of biosimilar ustekinumab." Def. Br. 13. J&J supports its argument by citing two paragraphs of the purchasers' complaint. Def. Br. 13 (citing ¶¶ 165-66). But those paragraphs explain that *J&J* had no competitive use for the Momenta patents, not that biosimilars could design around them. Just so, when J&J moved for a preliminary injunction against Amgen to keep it completely off the market, J&J used only the Momenta patents as the

[46] Table 2 of the amended complaint lists six biosimilar manufacturers who have settled with J&J. Since the purchasers filed the amended complaint, a seventh biosimilar settled with J&J. All these biosimilar manufactures have applied for FDA approval. *See* Ex. B.

[47] *Cf. Takeda Pharms. USA, Inc. v. West-Ward Pharm. Corp.*, No. 14-1268-SLR, 2014 WL 5088690 (D. Del. Oct. 9, 2014) (granting TRO preventing launch of a generic product for *all* indications despite the fact that the generic obtained FDA approval and sought to market only the non-patented indication).

legal basis to do so. ¶ 196. The Momenta patents were sufficient to exclude biosimilar competition.

II. J&J's acquisition of the '307 patent through fraud on the PTO constitutes unlawful monopolization of the market for ustekinumab.

A. The antitrust laws prohibit the acquisition of patents through fraud.

Patent prosecutors have a "fundamental" duty to prosecute their patent applications before the PTO with "candor, good faith, and honesty."[48] As this Court has recognized, "The vital importance of this duty cannot be overstated. Without it, the edifice of patent law cannot stand."[49] Pursuant to this duty, patent prosecutors must disclose "*all* information known to be material to patentability,"[50] including that which "refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability."[51] Patent prosecutors are also prohibited from "[m]ak[ing] a false statement of fact or law" and from "[f]ail[ing] to disclose to the tribunal legal authority . . . known to the practitioner to be directly adverse to the position of the client."[52]

In *Walker Process*, the Supreme Court held that where a patent applicant obtains a patent through fraud and enforces it to block competition, injured parties can recover damages for monopolization.[53] To prove *Walker Process* fraud, a plaintiff must show the defendant knowingly and willfully made (1) "a false representation or deliberate omission of a fact material

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[48] *Semiconductor Energy Lab'y Co., Ltd. v. Samsung Elecs. Co., Ltd.*, 4 F. Supp. 2d 477, 480 (E.D. Va. 1998), *recons. denied*, 24 F. Supp. 2d 537 (E.D. Va. 1998), *aff'd*, 204 F.3d 1368 (Fed. Cir. 2000); *see also Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949).

[49] *Semiconductor*, 4 F. Supp. 2d at 480.

[50] 37 C.F.R. § 1.56(a) (emphasis added).

[51] 37 C.F.R. § 1.56(b); *see also* 37 C.F.R. § 11.303(d); M.P.E.P. § 2001.

[52] 37 C.F.R. § 11.303(a).

[53] *Walker Process*, 382 U.S. at 177.

to patentability," (2) "with the intent to deceive," (3) "on which the examiner justifiably relied in granting the patent," and (4) "but for which misrepresentation or deliberate omission the patent would not have been granted."[54] An omission may constitute a material misrepresentation if the plaintiff alleges "intent separable from the simple fact of the omission."[55] Though Rule 9(b) governs *Walker Process* allegations, a plaintiff need not be clairvoyant: "intent, knowledge, and other conditions of a person's mind may be alleged generally."[56] "The characterization of a state of mind, after all, does not lend itself to detailed pleading."[57]

B. The complaint adequately alleges J&J procured the '307 patent through fraud.

The purchasers allege that J&J violated *Walker Process* by misrepresenting to the PTO that ustekinumab *unexpectedly* offered an effective treatment for UC. The priority date for J&J's patent application 16/580,509, which issued as the '307 patent, is September 24, 2018. ¶ 132. Any public information—including published medical journal articles and clinical trial protocols—available prior to that date can be used as evidence that the invention J&J sought to patent was not novel and thus not patentable. J&J, the named '307 inventors, and attorney who prosecuted it (Eric Dichter) were aware of, and affirmatively withheld or misrepresented, pre-September 2018 prior art that rendered J&J's application, and the resulting patent, invalid.

First, J&J attorney Eric Dichter and the named inventors were aware that J&J's own clinical trial protocol for use of Stelara to treat UC (NCT 236) revealed that the very invention J&J sought to patent—the use of ustekinumab to treat UC—was expected. Public NCT 236

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[54] *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998).

[55] *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347 (Fed. Cir. 2007).

[56] Fed. R. Civ. P. 9(b).

[57] *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 228 (1st Cir. 2004), *abrogated on other grounds by Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662 (2008).

materials state that "considering the similarities in the genetics and biology of UC and Crohn's disease, *it is reasonable to assume that ustekinumab will also be effective in UC*." ¶ 122 (quoting J&J's clinical trial protocol). Indeed, J&J relied on the similarities between Crohn's and UC as a justification for *skipping* Phase 2 trials for UC approval. *Id.* J&J's motion does not even attempt to argue that NCT 236 did not anticipate the '307 patent and render it invalid.

At the time J&J filed the '307 application, controlling law was clear that public clinical trial disclosures, like NCT 236, can invalidate patent applications. A 2012 Federal Circuit decision held that a clinical trial protocol, like NCT 236, that publicly discloses use of a drug to treat a particular disease renders a later patent application covering that use unpatentable.[58]

Attorney Dichter knew NCT 236 existed: he referenced it in the '307 application's specification.[59] However, he did not submit a copy of this key piece of prior art to the PTO until *after* the examiner located it for himself[60] and denied the application on the basis of its public disclosures. Nonetheless, attorney Dichter took J&J's deception a step further and affirmatively told the patent examiner—despite J&J's statements in NCT 236—"it would not have been obvious" that ustekinumab would successfully treat UC. ¶ 143. Relying on this misrepresentation, the patent examiner issued the '307 patent. ¶ 150.

Second, J&J—through its inventors and attorney—withheld published studies disclosing that ustekinumab was effective in treating UC. ¶ 140. As detailed in the complaint: (1) in February 2017, a Spanish study (the Afonso paper) showed that ustekinumab could be

[58] *See In re Montgomery*, 677 F.3d 1375, 1382 (Fed. Cir. 2012).

[59] *See* Patent File Wrapper at 64 (citing NCT 236).

[60] *See* Patent File Wrapper at 246 (Information Disclosure Statement disclosing a copy of NCT 236 after the examiner's rejection); *see also Longhorn Vaccines & Diagnostics, LLC v. Spectrum Sols. LLC*, 564 F. Supp. 3d 1126, 1140 (D. Utah 2021) (at the motion to dismiss stage, courts can take judicial notice of and rely on PTO submissions that the plaintiffd reference in the complaint).

effectively used to treat patients with UC, ¶ 125; (2) in January 2018, a German study (the Ochsenkühn paper) showed the same, ¶ 127; and (3) in February 2018, a Swiss study (the Kolios paper) reached the same conclusion. ¶ 128. These published articles constituted material prior art that rendered J&J's '307 application obvious under 35 U.S.C. § 103.

Even without discovery, evidence suggests J&J knew about these articles. J&J's analogous European patent—which it applied for on the *same day* it applied for the '307 patent before the PTO—lists the Ochsenkühn paper as reference on the second page.[61] Additionally, the primary authors of the Kolios and Ochsenkühn papers each disclosed that they were investigators, speakers, and/or advisors for J&J (specifically, Janssen) *before* the relevant prior art was published.[62] J&J is one the world's largest pharmaceutical companies. The suggestion that J&J did not know about research concerning its most profitable drug, conducted by researchers it had an existing relationship with and who had studied the drug for years, is risible. *See* Def. Br. 18-19.[63]

J&J's distortion of NCT 236 and its anticipatory (*i.e.*, invalidating) effect as well as J&J's omission of prior art articles disclosing ustekinumab's efficacy in treating UC constitute misrepresentations of material fact. At the motion to dismiss stage, attorney Dichter's failure to

[61] EP 3883606 at 2 (filed Sept. 24, 2019). This fact is not alleged in the purchasers' amended complaint, as it was discovered after filing. The purchasers could amend their complaint, or the Court could take judicial notice of this fact. *See Mary Lou Sullivan v. McGill & Hassan, PA*, 2019 WL 8918903, at *3 n.3 (E.D. Va. Sept. 30, 2019).

[62] *See* Antonios G.A. Kolios, et al., *Swiss S1 Guidelines on the Systemic Treatment of Psoriasis Vulgaris*, 4 Dermatology 232 (2016) (author of Kolios paper disclosing in a 2016 article about using ustekinumab for psoriasis that he served as an "investigator, speaker, and/or advisor" for Janssen); Thomas Ochsenkühn, et al., *Clinical outcomes with ustekinumab as rescue treatment in therapy-refractory or therapy-intolerant ulcerative colitis*, 8 United European Gastroenterology Journal 1, 91-98 (2020) (Dr. Ochsenkühn disclosing he had "received travel grants, honoraria for advisory activities and lecture fees from Janssen").

[63] *See Short*, 87 F.4th at 614 ("draw all reasonable inferences in favor of the plaintiff").

submit the NCT 236 protocol as prior art with the '307 application, his failure to disclose directly on-point legal authority, his misrepresentation of what J&J expected when it published the NCT 236 protocol, and his failure to disclose known, relevant prior art sufficiently evince his intent to deceive the PTO. J&J does not contest that the PTO "act[ed] in justifiable reliance on"[64] attorney Dichter's representations. Nor does J&J contest that it asserted the '307 patent against Amgen and other biosimilar competitors before settling with them to keep their products off the market.

C. The law and facts rebut J&J's *Walker Process* arguments.

1. Attorneys may argue, but they may not lie.

While attorneys are entitled to present their case to the PTO, and good faith *argument* does not give rise to inequitable conduct, "there is a line between legitimate advocacy in accordance with the duty of candor, and advocacy that the applicant surely knows has a propensity to mislead the examiner."[65] The complaint sufficiently alleges that J&J and attorney Dichter crossed that line.

First, the complaint alleges that, in response to the patent examiner's proper rejection of the patent application, attorney Dichter falsely stated—multiple times—that it would not have been obvious (*i.e.*, it was surprising) that ustekinumab would successfully treat UC. ¶¶ 143, 147. These statements are not attorney argument; attorney Dichter did not simply "attempt[] to

[64] *C.R. Bard*, 157 F.3d at 1364.

[65] *Semiconductor*, 4 F. Supp. 2d at 495 n.36; *id*. at 495 (rejecting inventor's attempts to distinguish a material article as "not only invalid, but also inconsistent with its own position on the subject" based, in part, on his prior statements lauding the importance of the article); *Apotex Inc. v. UCB, Inc.*, 763 F.3d 1354, 1362 (Fed. Cir. 2014); *ParkerVision, Inc. v. Qualcomm Inc.*, 924 F. Supp. 2d 1314, 1320 (M.D. Fla. 2013); *Bristol-Myers Squibb Co. v. Ben Venue Lab'ys*, 90 F. Supp. 2d 522, 534 (D.N.J. 2000). J&J's cited case law does not contradict this distinction. For example, in *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007), the Federal Circuit distinguished "attorney argument, attempting to distinguish the claims from the prior art," from "unreasonable interpretations of the [at issue] Reference."

distinguish [the '307] patent from prior art." Def. Br. 16. Rather, he made statements of fact that *directly conflict* with J&J's NCT 236 protocol, including its representation that given the similarities between Crohn's and UC, "it is reasonable to assume that ustekinumab will also be effective in UC." ¶¶ 120-22. Taking "one position before the PTO, and another before the FDA" is "prohibited under the [PTO's] materiality standard."[66] J&J's claim that it was uncertain whether ustekinumab would effectively treat UC is false in light of its prior statements. Indeed, J&J now makes no attempt to argue that NCT 236 did *not* anticipate the '307 patent.

In *American Sales Co. v. Pfizer*, this Court rejected a pharmaceutical company's similar attempts to re-characterize attorney misrepresentation as argument.[67] There, the plaintiff alleged that Pfizer misrepresented certain precepts of patent law to the examiner. Pfizer, like J&J here, countered that it was merely making "legal argument."[68] This Court rejected the claim and denied Pfizer's motion to dismiss because the plaintiff sufficiently alleged that Pfizer knew its "arguments" were "misleading, and possibly false."[69] So too here. The direct conflict between J&J's statements regarding ustekinumab's expected efficacy in NCT 236 and attorney Dichter's statements to the patent examiner show that J&J knew its PTO arguments were false. At the very least, it is an inference the must be credited on a motion to dismiss.

Second, the complaint sufficiently alleges that attorney Dichter concealed and misrepresented controlling legal authority. In *In re Montgomery*, the Federal Circuit held that a clinical trial protocol describing the use of a drug to treat a particular disease inherently

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[66] *Bristol-Myers*, 90 F. Supp. 2d at 534.

[67] Order at 12, *American Sales Co., LLC v. Pfizer, Inc.*, 2:14-cv-00361-AWA-DEM, ECF No. 73 (E.D. Va. Nov. 6, 2015) (holding that "circumstantial evidence is sufficient to establish the intent element of common-law fraud" (internal quotation marks omitted)).

[68] *Id.* at 4.

[69] *Id.* at 12.

anticipates a later patent claiming that use.[70] Attorney Dichter failed to disclose this controlling authority, in violation of his duty of candor. ¶ 141.[71] J&J knew *Montgomery*'s holding when it applied for the '307 patent: J&J was a party to an *inter partes* proceeding in which *Montgomery* was cited.[72] And it is reasonable to assume that attorney Dichter, a seasoned patent attorney who prosecuted more than 100 patents on Janssen's behalf, was also aware of it. ¶ 136.[73]

Attorney Dichter's failure to disclose this case law was not attorney argument, but a material omission of controlling legal authority. Patent prosecution is not analogous to zealous advocacy in court: PTO rules *require* attorneys to disclose "*all* information known to be material to patentability,"[74] including "legal authority . . . known to the practitioner to be directly adverse to the position of the client."[75] Indeed, the Ninth Circuit reversed a district court's grant of summary judgment on the question of *Walker Process* intent where a drug company failed to disclose a relevant case citation (and translation of a prior art patent).[76] The court explained that where facts are susceptible to more than one reading, the claim cannot be dismissed.

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[70] *See In re Montgomery*, 677 F.3d at 1382.

[71] *See* 37 C.F.R. § 1.56(b); 37 C.F.R. § 11.303; *see, e.g.*, *U.S. Dept. of Housing & Urban Dev. v. Cost Control Mktg. & Sales Mgmt. of Va.*, 64 F.3d 920, 925 (4th Cir. 1995) (finding defendants' failure to cite contrary legal authority to be contrary to the duty of candor).

[72] *See* Janssen Prelim. Response, *Lupin v. Janssen*, IPR2015-01030 (PTAB July 20, 2015), Paper 9. *Montgomery* was also cited in another Janssen IPR in February 2020, before J&J met with the patent examiner to discuss the rejection. *See* Pet., *Mylan v. Janssen*, IPR2020-00440, 2020 WL 700247 (PTAB Feb. 7, 2020). The purchasers could amend their complaint to include these facts, or the Court could take notice of them. *See Sullivan*, 2019 WL 8918903, at *3.

[73] *See* https://ppubs.uspto.gov/pubwebapp/ (search for "(eric).att. NEAR (dichter).att."). Unless Mr. Dichter has a perfect track record, the number of applications or defenses Mr. Dichter has been involved in is likely much higher, as not all patent applications are issued.

[74] 37 C.F.R. § 1.56(a) (emphasis added).

[75] 37 C.F.R. § 11.303; *see supra* n.71.

[76] *Kaiser Found. Health Plan, Inc. v. Abbott Lab'ys, Inc.*, 552 F.3d 1033, 1048-49 (9th Cir. 2009).

Third, J&J argues that its misrepresentations regarding NCT 236 were not fraud because the examiner found NCT 236 and was therefore "free to draw his own conclusions . . . ." Def. Br. 16. But as the Federal Circuit and this Court have affirmed, a patent examiner's access to reference does *not* negate a defendant's misrepresentations regarding that reference.[77] "Defendants ha[ve] a duty to point out the statements in the [] article which were contradictory to the statements in the patent and explain them."[78]

2. The purchasers adequately allege that the withheld prior art was material.

J&J's second attack on the health benefit providers' *Walker Process* allegations boils down to a complaint that they did not cite patent claims numbers in their complaint. Def. Br. 17. But the purchasers do not cite claim numbers because they allege that the omitted prior art studies render *all* the '307 patent's claims obvious. ¶ 152.

Claim 1 is the heart of the "invention," and it lays stake to a method of treating UC.[79] As the purchasers' complaint details, the prior art studies (the Alfonso, Ochsenkühn, and Kolios papers) revealed that ustekinumab could effectively treat UC *before* the '307 patent's priority

[77] *See In re Rhone-Poulenc Rorer, Inc.*, 178 F.3d 1309, at *3 (Fed. Cir. 1998) (unpublished) (holding that just because the patent examiner had the relevant prior art before him did not immunize the patent applicant's misleading statements about that art); *Ryan-House*, Ex. C at 7 ("[T]he PTO's knowledge of the existence of [a prior art] patent does not equate with the knowledge that the subsequent patents were a replication of prior art." (quoting *Norton v. Curtiss*, 433 F.2d 779, 794 (3d Cir. 1970)).

[78] *Rhone-Poulenc*, 178 F. 3d at *3 (citing *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571-72 (Fed. Cir. 1983)). *Rhone* affirmed the district court's conclusion that the patentee committed fraud even though "examiner did unearth the [relevant] article on his own." *Id.* at *1.

[79] U.S. Patent No. 10,961,307 col. 119 ll. 33-65. The '307 patent has 34 claims, where Claims 1, 19, 33, and 34 are the independent claims and the remaining claims are dependent claims. *See* U.S. Patent No. 10,961,307. Independent claims 19, 33, and 34 describe methods of administration—the subcutaneous and intravenous administration of the drug—that doctors had used for years to treat patients with ustekinumab (and were therefore known methods that would have been obvious to a person of skill in the art). The dependent claims merely describe ustekinumab or the endpoints. *See* U.S. Patent No. 10,961,307 cls. 1-34.

date, rendering its claims obvious. ¶¶ 125, 127, 128. The complaint directly quotes the relevant portions of these prior art studies. *Id*. The purchasers' direct citations to the specific portions of the prior art references meet Rule 9(b)'s particularly requirement.[80]

The materiality of these papers is obvious. The PTO initially rejected *all* the '307 patent's claims as anticipated by a clinical trial protocol that stated ustekinumab would effectively treat UC. ¶ 141. Put another way, the examiner zeroed in on prior art showing ustekinumab was an effective treatment for UC as a basis for denying *all* the '307 patent's claims. Prior art suggesting, let alone showing, the same was highly material to whether those claims issued.

J&J cites *Exergen Corp. v. Wal-Mart Stores, Inc.*, in support of its position that the purchasers must talismanically cite claims numbers for their allegations to survive.[81] However, as J&J recognizes, the rationale underlying this requirement is: "[s]uch allegations are necessary to explain both 'why' the withheld information is material and not cumulative, and 'how' an examiner would have used this information in assessing the patentability of the claims."[82] Here, the purchasers' pleadings meet both the "how" and "why": the papers are material because, as demonstrated by the examiner's denial, whether prior art showed ustekinumab to be effective in treating UC was dispositive for its issuance. And the examiner would have used this information just as it did NCT 236—to reject all the patent's claims. ¶ 141. The sufficiency of the purchasers' *Walker Process* allegations should not hinge on incantation of the words "the prior art renders all claims of the '307 patent obvious." However, should the Court agree with J&J that the law

[80] J&J's cited case law does not require more. For example, *Fred Hutchinson Cancer Rsch. Ctr. v. BioPet Vet Lab, Inc.*, dismissed the plaintiffs' claim, in part, because they failed to "indicate where within those [*prior art] references* the material information may be found." No. 2:10-CV-616, 2011 WL 2551002 at *3 (E.D. Va. Jun. 27, 2011) (emphasis added).

[81] Def. Br. 17 (citing 575 F.3d 1312, 1329 (Fed. Cir. 2009)).

[82] *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d at 1329-30.

requires the purchasers to state as much, they request leave to do so.

3. J&J was aware of invalidating prior art.

The complaint alleges, in detail, that J&J knew about invalidating prior art. In fact, the health benefit providers' allegations go beyond what the law requires at this stage. In analyzing a motion to dismiss, "[g]enerally, lack of proof of intent within the four corners of the pleading is not a reason to dismiss a complaint."[83] "Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence."[84] As a result "to dismiss on [lack of intent], the defendant must show that the Plaintiff has failed to allege *any facts* that can support an inference of bad faith or an intent to deceive."[85]

Here, J&J disclosed the Ochsenkühn paper in its analogous European Patent (EP 3 883 606 B1). The second page of the patent—which J&J applied for on the exact same day as the U.S. patent—lists the Ochsenkühn paper as a reference.[86] Nonetheless, in prosecuting the '307 patent, attorney Dichter affirmatively represented that "[p]rior to the present invention, no studies had been conducted with ustekinumab for [UC]." ¶ 140. J&J's failure to tell the PTO about a reference *listed in its own analogous European Patent* "support[s] an inference of bad

[83] *In re Effexor XR Antitrust Litig.*, No. 11-5479 PGS, 2014 WL 4988410, at *26 (D.N.J. Oct. 6, 2014), *rev'd and remanded sub nom. In re Lipitor Antitrust Litig.*, 868 F.3d 231, 249 (3d Cir. 2017) (reversed on other grounds); *Loestrin*, 261 F. Supp. 3d at 341 ("[C]ourts have cautioned that '[s]cienter or intent to defraud is usually an issue of fact that should not typically be resolved on a pretrial motion.'" (quoting *Effexor*, 2014 WL 4988410, at *26)).

[84] *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 at 1290 (Fed. Cir. 2011); *see also* Order at 12, *American Sales Co., LLC v. Pfizer, Inc.*, 2:14-cv-00361-AWA-DEM, ECF No. 73 (E.D. Va. Nov. 6, 2015) (holding that "circumstantial evidence is sufficient to establish the intent element of common-law fraud" (internal quotation marks omitted)).

[85] *In re Effexor*, 2014 WL 4988410 at *26 (emphasis added).

[86] EP 3883606 at 2 (filed Sept. 24, 2019).

faith or an intent to deceive" at the motion to dismiss stage.[87] Further, as detailed above, the relationship between J&J and the authors of the prior art articles supports an inference that J&J knew about these public works (and therefore should have submitted them to the PTO). To the extent that J&J challenges the sufficiency of the purchasers' allegations as to J&J's intent generally, the purchasers' alleged facts are more than sufficient.[88]

4. Indirect purchasers have standing to bring *Walker Process* claims.

Next, J&J seeks immunity on the grounds that the plaintiffs are indirect purchasers. According to J&J, this fact vitiates the purchasers' "standing to challenge alleged fraud on the PTO." Def. Br. 19. J&J ignores numerous decisions—*including one from this Court*—sustaining indirect purchasers' state law claims alleging similar fraud on the PTO.[89] J&J's principal case, *In re K–Dur*,[90] was later rejected by a better reasoned decision: *In re DDVAP Indirect Purchaser*

[87] *In re Effexor*, 2014 WL 4988410 at *26 (emphasis added). J&J's cases concern dismissals of inequitable conduct claims where the pleading party did "nothing more than recite the generic elements of the [inequitable conduct] defense," without any "particularized factual bases whatsoever." *Mike's Train House, Inc. v. Broadway Ltd. Imports, LLC*, No. CIV. JKB-09-2657, 2011 WL 2415014, at *4 (D. Md. June 10, 2011). Such generic recitation is not at issue here.

[88] *See supra* Section II.B (last paragraph); *Kaiser*, 552 F.3d at 1048-49 (a drug company's failure to submit (1) an English translation of a relevant, Japanese prior art reference, and (2) a relevant case citation were facts sufficient to suggest intent at the summary judgment stage).

[89] *See, e.g.*, *Ryan-House*, Ex. C at 10; *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 355 F. Supp. 3d 145, 150 (E.D.N.Y. 2018); *In re Lipitor Antitrust Litig.*, 336 F. Supp. 3d 395 (D.N.J. 2018); *In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 217 (S.D.N.Y. 2012) ("state-law *Walker Process*-type antitrust and/or consumer protection law claims are not preempted"); *Loestrin*, 261 F. Supp. 3d at 357 ("[S]tate law claims based on *Walker Process*-type fraud do not frustrate the purposes or objectives of federal patent law for the same reasons their federal counterparts do not."). Another instructive precedent from this Circuit is *Koch Agronomic Servs., LLC v. Eco Agro Res. LLC*, No. 1:14CV679, 2015 WL 5712640 (M.D.N.C. Sept. 29, 2015). In *Koch*, a infringement defendant asserted counterclaims, including Sherman Act and NC consumer protection claims based on misrepresentations to the PTO, and the court sustained both state law claims, applying *Walker Process*'s logic. *Id.* at *14.

[90] *See* Def. Br. 19 (citing No. 01-1652, 2007 WL 5297755, (D.N.J. Mar. 1, 2007)).

Antitrust Litigation.[91] Because J&J cannot point to a Fourth Circuit decision holding that indirect purchasers lack standing—and this Court has held the opposite—J&J's argument fails.

III. The purchasers' claims run afoul of neither *Noerr Pennington* nor *Actavis*.

J&J raises the *Noerr-Pennington* doctrine and reverse payment precedent to argue that the purchasers do not allege an actionable antitrust violation. *See, e.g.*, Def. Br. 20, 22. But *Noerr-Pennington* and the reverse payment case law are irrelevant here, where the basis for J&J's antitrust *liability* is its acquisition of the Momenta patents and '307 patent even if the purchasers' antitrust *injury* flows from J&J's settlements with biosimilar competitors.

The First Circuit's decision in *Amphastar* not only clarifies the import of this distinction, but does so with analogous facts (down to the parties at issue). In *Amphastar*, a generic manufacturer (Amphastar) sued two of its competitors (Sandoz and Momenta), alleging that they failed to disclose to the United States Pharmacopeial Convention (USP) that a proposed testing method might be covered by Momenta's pending patent application. The USP adopted the method and the FDA required Amphastar to comply with it. Sandoz and Momenta then sued Amphastar for violating Momenta's patent and Amphastar counterclaimed under Sherman Act §§ 1 and 2, seeking damages for the period that the suit kept it off the market.[92] The district court dismissed Amphastar's antitrust claims, holding that because its injuries arose from the patent litigation and resulting injunction, *Noerr* provided complete immunity and barred those claims.

Not so fast, said the First Circuit. "Courts have recognized that '[t]here is an important

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[91] *In re DDAVP*, 903 F. Supp. 2d at 217. J&J's reliance on *Farag v. Health Care Serv. Corp.* is also misplaced; *Faraq* stands for the unremarkable notion that "*Walker Process* standing should be interpreted in light of regional circuit law on antitrust standing." No. 17-2547, 2017 WL 2868999, at *5 (N.D. Ill. July 5, 2017).

[92] *Amphastar Pharmaceuticals Inc. v. Momenta Pharm., Inc.*, 850 F.3d at 52, 54 (1st Cir. 2017). The USP is a private rate setting organization, so petitions to it do not fall under *Noerr*'s ambit.

difference, for purposes of the *Noerr-Pennington* doctrine, between using litigation . . . as *a basis of antitrust liability* and *awarding damages* for efforts to use the courts to carry out private cartel agreements.'"[93] As the First Circuit explained, "[t]he mere existence of a lawsuit does not retroactively immunize prior anti-competitive conduct."[94] Sandoz and Momenta's infringement suit could not "'itself be the antitrust violation without invoking *Noerr*.'"[95] But where "'the antitrust *violation* is intentional deception of the standard-setting organization,' the mere fact that the alleged *damages* are based, in part, on a lawsuit seeking an injunction does not 'defeat the antitrust claim based on conduct before the standard-setting organization.'"[96] In line with traditional causation analyses, the First Circuit correctly observed that "the antitrust violation need not be the sole cause of Amphastar's injury, so long as it was a material cause."[97]

J&J urges this Court to fall into the same trap as the *Amphastar* district court, claiming that *Noerr-Pennington* forecloses this antitrust action because the purchasers' injuries flow from J&J's patent suit against Amgen. Def. Br. 20-21. But the allegations should be sustained for the exact same reason as Amphastar's: the antitrust violation is not the patent infringement lawsuit, but J&J's *prior acquisition* of the Momenta patents and the '307 patent.[98] J&J seems to recognize this distinction, but it makes no attempt to counter based on law. Def. Br. 22 n.12.

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[93] *Id.* at 57 (emphasis added) (quoting *Premier Elec. Constr. Co. v. Nat'l Elec. Contractors Ass'n, Inc.*, 814 F.2d 358, 374 (7th Cir. 1987)).

[94] *Id.* (citing *Walker Process*, 382 U.S. at 177; *Singer*, 374 U.S. at 196-97; *Primetime 24 Joint Venture v. Nat'l Broad. Co., Inc.*, 219 F.3d 92, 102-03 (2d Cir. 2000)).

[95] *Id.* (quoting 2 Hovenkamp et al., IP & Antitrust § 35.05[B] (3d ed. 2017)).

[96] *Id.* (emphasis added) (quoting 2 Hovenkamp, IP & Antitrust § 35.05[B]); *see* Br. of Amicus Curiae Federal Trade Commission at 11 (FTC Br.), 850 F.3d 52 (1st Cir. 2017) ("*Noerr* does not retroactively protect unlawful agreements or schemes to acquire, maintain, or jointly exercise market power that defendants subsequently exploit through litigation.").

[97] *Amphastar*, 850 F.3d at 57-58 (internal quotation marks omitted).

[98] J&J does not contest that *Walker Process* fraud is an exception to *Noerr*. Def. Br. 21-22.

Instead, J&J offers only *ipse dixit* that this distinction does not remove the case from *Noerr*'s ambit. But, as in *Amphastar*, "the mere fact that [the purchasers'] alleged damages are based, in part, on a lawsuit seeking an injunction does not defeat the antitrust claim."[99]

The *Amphastar*'s reasoning is well supported by other circuit and district courts.[100] For example, *Amphastar* relied on a Seventh Circuit decision that emphasizes the same distinction between an antitrust violation and damages flowing from that violation.[101] The Ninth Circuit has also held that if a plaintiff "can prove that the defendants engaged in activities which violated the antitrust laws, those violations do not become immune simply because the defendants used legal means . . . to enforce the violations."[102] "An antitrust violation does not enjoy [*Noerr*] immunity simply because an element of that violation involves an action which itself is not illegal."[103] Instead, "when considered with the entire monopolistic scheme which preceded them . . . [litigation] may be considered as having been done to give effect to the unlawful scheme."[104]

In addition to its *Noerr* argument, J&J contends that its settlements with other biosimilar manufacturers are not exclusionary conduct. This argument, again, misses the point: the

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[99] *Amphastar*, 850 F.3d at 57 (internal quotation markets omitted).

[100] Other circuits have recognized that anticompetitive conduct is not immunized if damages flow through litigation. *See infra* n. 101-103; *see also Kobe, Inc. v. Dempsey Pump Co.*, 198 F.2d 416, 425 (10th Cir. 1952), *cert. denied*, 344 U.S. 837 (1952); *Bio-Rad*, 483 F. Supp. 3d at 54-55 (collecting cases and finding that "litigation can constitute antitrust injury, but not antitrust harm"); FTC Br. at 12-13 (citing "Supreme Court cases that have long held, post-*Noerr*, that antitrust claims are not foreclosed by patent infringement lawsuits brought to exploit market power acquired, maintained, or jointly exercised through the challenged antitrust misconduct.").

[101] *Premier Elec. Constr. Co. v. Nat'l Elec. Contractors Ass'n, Inc.*, 814 F.2d 358, 374 (7th Cir. 1987) ("There is an important difference, for purposes of the *Noerr-Pennington* doctrine, between using litigation (or other petitions to the government) as a basis of antitrust liability and awarding damages for efforts to use the courts to carry out private cartel agreements.").

[102] *Clipper Exxpress v. Rocky Mtn. Motor Tariff Bureau, Inc.*, 690 F.2d 1240, 1264 (9th Cir. 1982).

[103] *Id.* at 1263.

[104] *Kobe*, 198 F.2d at 425.

purchasers do not allege the *settlements* violate the Sherman Act. As result, J&J's discussion of the legality of "normal settlements," *Actavis,* and other reverse payment case law is irrelevant.

IV. The purchasers assert plausible claims under state law.

As J&J acknowledges, proposed class representative CareFirst purchased Stelara for its members in 45 states and D.C., *nearly every jurisdiction* included in the nationwide class. ¶ 300 & Table 3. J&J contends, however, that CareFirst may not pursue class claims in states where it does not plead purchases. Def. Br. 28. The Fourth Circuit has rejected this exact argument and held that a proposed class of health benefit providers could assert claims under the laws of states even where they did not have purchases: "Since those counts of the complaint define *class members'* claims, they may be considered" and assessed under the Rule 23 class certification inquiry.[105] All other appellate courts that have addressed this issue agree.[106]

J&J next claims that the consumer protection counts "rely on generalized allegations" and "rote legal conclusions." Def. Br. 28. The purchasers' consumer protection allegations incorporate all the substantive allegations of the complaint and then outline how those allegations satisfy the elements of the pleaded statutes. ¶¶ 375-393. J&J's argument both misstates the pleading standard and misunderstands the practice of pleading nationwide class claims. Courts facing similar class actions routinely hold that consumer protection claims survive when they "incorporate by reference the entire complaint, which contains many allegations of

[105] *Mayor of Baltimore v. Actelion Pharm. Ltd.*, 995 F.3d 123, 134 (4th Cir. 2021); *see also Zetia*, 2019 WL 1397228, at *23, *report and rec. adopted as modified*, 400 F. Supp. 3d 418, 433 (rejecting the same argument and explaining that the Rule 23 inquiry will determine whether the named class representatives can assert claims on behalf of absent class members).

[106] *See Langan v. Johnson & Johnson Consumer Cos.*, 897 F.3d 88, 95 (2d Cir. 2018); *In re Asacol Antitrust Litig.*, 907 F.3d 42, 49 (1st Cir. 2018); *Morrison v. YTB Int'l, Inc.*, 649 F.3d 533, 536 (7th Cir. 2011).

unfair competition and anticompetitive injury caused by Defendants' . . . conduct."[107]

J&J next challenges our Illinois and Massachusetts consumer protection claims, arguing that we may not use them to make an "end-run" around the respective states' prohibition on indirect purchaser antitrust damages. Def. Br. 27. J&J is incorrect as to both states. Illinois law allows indirect purchaser class actions in federal court under both its antitrust and consumer protection laws.[108] Massachusetts "allows *any* person who has been injured by trade or commerce *indirectly* affecting the people of [Massachusetts] to bring a cause of action."[109]

The purchasers' unjust enrichment claims also are not an "end-run" around indirect purchaser bars. Rather, "the concerns that motivate *Illinois Brick* . . . are not implicated in the context of unjust enrichment claims because the very nature of such claims requires a focus on the gains of the defendants, not the losses of the plaintiffs."[110]

CONCLUSION

The health benefit providers request that this Court deny J&J's motion in its entirety.

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[107] *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2015 WL 5458570, at *15 (D. Mass. Sept. 16, 2015); *see also Loestrin*, 261 F. Supp. 3d at 360 (collecting cases); *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 2:18-MD-02836, ECF No. 130, ¶¶ 350-59 (E.D. Va. Sept. 13, 2018) (indirect purchaser complaint listing state statutes and incorporating substantive allegations by reference); *Zetia*, 400 F. Supp. 3d at 436-441 (sustaining multiple consumer protection claims pleaded in this way).

[108] *See Zetia*, 400 F. Supp. 3d at 434 (concluding IL class action bar does not apply in federal court); *id.* at 438 ("Because the court found that the EPPs' claims under Illinois's antitrust statute may proceed, the EPPs' claims under Illinois's consumer protection statute may also proceed.").

[109] *Ciardi v. F. Hoffmann-La Roche, Ltd.*, 436 Mass. 53, 58-60 (2002); *see also In re Interior Molded Doors Antitrust Litig.*, No. 3:18-cv-00718, 2019 WL 4478734, at *22 (E.D. Va. Sept. 18, 2019). Indeed, *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 700 (E.D. Pa. 2014), relied on by J&J, Def. Br. 27, recognizes *Ciardi* and explains that indirect purchasers may sue under Section 9 of the MA Consumer Protection Act—as the purchasers here do. ¶ 392(m) (Mass. Gen. Laws. ch. 93A, §§ 1, *et. seq.*).

[110] *In re Generic Pharm. Pricing Antitrust Litig.*, 368 F. Supp. 3d 814, 850 (E.D. Pa. Feb. 15, 2019) (quotations omitted). This argument is particularly bizarre as to the Connecticut, Maryland, and Rhode Island claims because J&J does not challenge the purchasers' antitrust claims for those states on indirect purchaser grounds. Def. Br. 27.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, William H. Monroe, Jr., certify that, on this date, the foregoing document was filed electronically via the Court's CM/ECF system, which will send notice of the filing to all counsel of record, and parties may access the filing through the Court's system.

Dated: April 2, 2024

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